No. 21-14325

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

STEVEN ABDOO, ET AL.,
Plaintiff-Appellants

v.

GLENMARK PHARMACEUTICALS, INC. USA, ET AL.
D*efendants-Appellees*

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

On Appeal from the United States District Court
for the Southern District of Florida

PERSONAL INJURY PLAINTIFFS-APPELLANTS' REPLY BRIEF

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Abdoo, et al. v. Glenmark Pharmaceuticals, Inc. USA, et al

CERTIFICATE OF INTERESTED PERSONS

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Plaintiff-Appellants hereby certifies that the previously filed Certificate remains correct.

Dated: November 8, 2024

Respectfully submitted,

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STATEMENT REGARDING ADOPTION OF BRIEFS OF OTHER PARTIES

The Personal Injury Appellants adopt the arguments set forth in the reply brief for the Generic-Only Plaintiffs in its entirety.

INTRODUCTION

The district court below treated every case as merged. That treatment impaired plaintiffs' appellate rights, overrode plaintiffs' due process rights to present their own expert witnesses, and, ultimately, destroyed the lower court's jurisdiction. That is because merger of cases necessarily combines the parties to the case, and here, doing so destroys complete diversity. This Court should enforce jurisdictional rigor and vacate the district court's judgments.

If this Court finds subject matter jurisdiction, it must address the district court's erroneous holding on *personal* jurisdiction. In a move reminiscent of the bad old days of substantive due process, the district court held that the Fourteenth Amendment's Due Process Clause renders California and Massachusetts' tort for negligent misrepresentation *unconstitutional*. The Brand Defendants acted in those states' markets extensively, advertising ranitidine, cultivating the market, and trumpeting its safety record. Plaintiffs then purchased ranitidine believing—based on those representations—that it was safe. The ranitidine then gave them cancer. The fact that Plaintiffs purchased *generic* ranitidine, which is by law identical to branded Zantac, has no jurisdictional relevance. The elements of negligent misrepresentation have never required the sale of a product, but rather require a misrepresentation that injures the plaintiff. That happened here, so there is plainly personal jurisdiction.

If the Court reaches the merits, it should reverse the district court on multiple grounds. The lower court's *Daubert* order places the bar so high that scarcely any expert could surmount it. Even though observational studies *never* opine on causation—that requires Bradford Hill analysis or a clinical trial—the district court faulted Plaintiffs' experts for drawing conclusions that study authors had not. Even though Zantac is banned worldwide because of the consensus on how dangerous NDMA is, the district court faulted Plaintiffs' experts for defying an imagined consensus that ranitidine is *safe*.

The extraordinarily lengthy *Daubert* order in this case has other hallmarks of improper gatekeeping. The district court larded up the order with more than a *dozen* alternative holdings for each expert, including many that fall apart at the slightest scrutiny. The larger problem, however, is what the order conveys about the judicial role. The district court saw itself as the arbiter of whether ranitidine causes cancer. It came to its "own understanding, based upon what it learned at the *Daubert* stage of these proceedings" about "the theoretical potential of ranitidine to cause cancer." MDL.Dkt.6622 at 5. And, once it had decided, it accepted *every* potential argument that could be used to exclude an expert. That entire approach was an abuse of discretion.

ARGUMENT

I. The District Court Lacked Diversity Jurisdiction And Violated Appellants' Due Process Rights.

The Generic-Only Reply brief chiefly addresses the lack of jurisdiction. However, the Brand Defendants' extraordinary series of arguments warrants a further response. Appellants changed their position after this Court rejected it and the district court treated the cases as merged. The Brand Defendants, however, have now changed their position *after prevailing* in this Court and below, without candidly explaining why.

A. Brand Defendants' Previously Successful Arguments Demonstrate That Merger Occurred, and Their New Arguments Are Flawed.

The Brand Defendants invoked merger in their motion to dismiss the *Cartee* appeal. In this Court's summary, Brand Defendants "ask[ed] us to dismiss the appeals of Mr. Cartee and Ms. William for lack of appellate jurisdiction because the orders dismissing the MPIC—which they *argue merged the personal injury cases against them*—are non-final and non-appealable." *Cartee v. Boehringer Ingelheim Pharms. Inc.*, No. 21-10305, 2022 WL 16729151, at *4 (11th Cir. Nov. 7, 2022) (emphasis added). In the Brand Defendants' words, because the cases were merged there was no final judgment until the district court "dismiss[es] the *entire* MPIC." CA11.No.21-10305.D.E.18 at 18 (emphasis added). An order dismissing all of Mr. Cartee's claims "would not be appealable while the MPIC remained pending"

because "thousands" of plaintiffs' "claims remain pending," and his case is merged with theirs. *Id.* at 9. On reply, they stuck to their guns, arguing that "**there is no final judgment because the MPIC remains pending**," and the dismissal of a short-form complaint would not end any action "because his SFC isn't the operative pleading." CA11.No.21-10305.D.E.34 at 17 (capitalization normalized); *see also id.* at 20 ("an order disposing of only Cartee's claims would be 'non-final'" because *other* claims remain in the operative pleading).

This Court agreed with the Brand Defendants that the *full* MPIC and short-form were the operative complaint. *Cartee*, 2022 WL 16729151, at *5. After persuading this Court of their position (to the detriment of Mr. Cartee, a party in both that appeal and in this one), the Brand Defendants now argue the cases did *not* merge, advocating a different legal standard *and* making diametrically opposed representations about the facts. Judicial estoppel should block Brand Defendants' maneuver. Their position is "clearly inconsistent" with the prior one; they persuaded this Court to dismiss Mr. Cartee's appeal based on their old position; and they have gained unfair advantage (namely, delaying appeals and harming Appellants' due process rights below). *See New Hampshire v. Maine*, 532 U.S. 742, 749-50 (2001) (stating the elements of judicial estoppel).

The Brand Defendants' new legal standard is that merger occurs only when "the parties and the court 'meant' to produce that result." Brand.Br. at 43 (quoting

Gelboim v. Bank of Am. Corp., 574 U.S. 405, 413 n.3 (2015)). It is fanciful to assert that the Supreme Court ever held that subject-matter jurisdiction turns on the subjective (and no doubt disparate) intentions of the court, dozens of Defendants, and *thousands* of individual Plaintiffs. "No merger occurs … when 'the master complaint is not meant *to be a pleading with legal effect* but only an administrative summary of the claims.'" *Gelboim*, 574 U.S. at 413 n.3 (quoting *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590-92 (6th Cir. 2013) (emphasis added). So long as the parties and court produce a master complaint "with legal effect," the claims and parties listed in that operative complaint become merged. This follows the ordinary rule that the operative complaint defines the claims and parties that are in that action. It of course does Brand Defendants no good to say diversity-destroying Plaintiffs intended to file their claims on the same pleading, but did not intend for that step to have any jurisdictional consequences.[1]

A myopic focus on the word "meant" in *Gelboim* also commits the forbidden sin of reading a judicial opinion like the words of a statute. *Loper Bright Enters. v.*

[1] Brand Defendants cite *In re 21st Century Oncology Customer Data Security Breach Litigation*, for the proposition that consent is the test for merger, but that case was about choice of law. 380 F. Supp. 3d 1243, 1259 (M.D. Fla. 2019). Parties can elect to proceed under forum law by consent, but this has nothing to do with merger. Two plaintiffs on the same complaint could have different choice of law or could consent to have the same law apply. Whether they are merged into one action is immaterial.

Raimondo, 144 S. Ct. 2244, 2281 (2024) (Gorsuch, J., concurring). In context, *Gelboim* announces a functional test for merger, and merger has jurisdictional consequences in diversity cases. *Gelboim* cannot sensibly be read to have smuggled into the United States Reports a repudiation of the ancient principle that "jurisdiction cannot be conferred by consent of the parties, but must be given by the law." *Town of Elgin v. Marshall,* 106 U.S. 578, 580 (1883); *Walker v. Taylor,* 46 U.S. 64, 67 (1847) (same).

The Brand Defendants also argue that the cases could not have merged because they do not "satisfy the standard for permissive joinder." Brand.Br. at 46. Appellants agree that the district court *should* not have merged the cases, and that doing so was legal error. But that point of agreement says nothing about whether the district court *did* merge the cases, which it plainly did under *Gelboim*.[2]

The Brand Defendants used to agree. Their factual representations now are the polar opposites of their previous positions on every material factor that bears on merger:

[2] An example may help. Suppose dozens of plaintiffs file a single complaint that patently flunks Rule 20, but the district court proceeds with the case, entering summary judgment on the merits. If the losing party pointed out on appeal that the district court lacked diversity jurisdiction, it would be no answer to argue that the parties were not *really* in the same case because the complaint violated Rule 20. True, the case *ought* to have been bounced on misjoinder grounds, but what happened and what should have happened are two different things.

Did the master complaint supersede the individual complaints?

- "[T]his MDL did not use a master complaint that 'superseded the individual pleadings.'" Brand.Br. at 44.
- "[T]he MPIC *did* 'supersede and replace' prior individual pleadings." CA11.No.21-10305.D.E.34 at 18; *see also id.* D.E.18 at 21 (similar).

Do objective factors from *Refrigerant* and *Bell* support merger?

- "[A]ll the evidence points to one conclusion: the parties and district court never intended or consented to merge," Brand.Br. at 43.
- The "actions did not 'retain[] their separate character'" and "[a]ll the relevant circumstances confirm this point." CA11No.21-10305.D.E.34 at 18; *see also* D.E.18 at 21-22 (marching through 5 factors and finding each one met).

If consent were even relevant (and it is not), did the Plaintiffs consent to merger?

- "Plaintiffs … did *not* consent to merge their individual cases into a single action." Brand.Br. at 45.
- "All plaintiffs consented to the merger." CA11.No.21-10305D.E.34 at 18 n.3.
- "Plaintiffs agreed in this Court's pre-trial orders to merge their individual claims with master pleadings, and they cannot now escape

the consequences of those orders simply because they now find it inconvenient." MDL.Dkt.3894 at 4-5.

Did the district court treat the cases as merged or individual?

- "[T]he district court's pretrial orders likewise treated each Plaintiff as having a separate, individual action." Brand.Br. at 45.
- "The district court set deadlines based on the MPIC," invited "'motions aimed' only at the MPIC," and "examined only the MPIC in granting the motions." CA11.No.21-10305.D.E.18 at 22.

B. The District Court Treated the Cases as Merged, Violating Appellants' Due Process Rights.

Contrary to their own previous representations *and* the district court's finding, Defendants now argue that the district court *treated* the cases as individual. The opposite is true. "The Court notes that each individual case in this MDL, *regardless of when it was filed*, utilizes the same MDL master pleadings and avails itself of the same MDL record evidence—the same pleadings and the same evidence that gave rise to the Court's *Daubert* decision." MDL.Dkt.6444 at 14 (emphasis added). The district court admitted to treating *every* case as having the same pleadings, claims, evidence, witnesses, and rulings, even if it was filed *after* the *Daubert* decision, and thus had no possibility of building an individual record. That is how the district court justified entering judgment against every Plaintiff, no matter when he or she first lodged a complaint. If that is *not* merger, it is something worse: a frank

admission to violating the maxim that "an MDL court's determination of the parties' rights in an individual case must be based on the same legal rules that apply in other cases, as applied to *the record in that case alone*." *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 841 (6th Cir. 2020).

Consider the pre-trial orders first. The district court required that the "[MPIC] together with the Short-Form Complaint shall be deemed the operative complaint." Brand.Br. at 44 (quotation marks omitted). Brand Defendants now argue that each plaintiff was "to selectively incorporate allegations from the MPIC into that Plaintiff's individual action and to supplement them with his or her own allegations." *Id.* Mr. Cartee previously argued something similar: "the operative pleading here is not the MPIC. The MPIC is a menu of available defendants, facts, and counts that individuals *may* incorporate into SFCs, and, *so incorporated*, it becomes the pleading for *that* plaintiff." CA11.No.21-10305.D.E.23 at 32. But this Court rejected Mr. Cartee's argument, concluding that "the combination of the MPIC and his SFC," not only the sections incorporated by the SFC, were the "operative complaint." *Cartee*, 2022 WL 16729151, at *5.

The distinction between the MPIC *as incorporated* and the entire MPIC is crucial and dispositive. If the operative pleading is the SFC plus the incorporated portions of the MPIC, then dismissing the claims of one plaintiff would cover every claim in the operative complaint, ending the case. The point of Brand Defendants'

successful argument was that "an order disposing of only Cartee's claims would be 'non-final,'" CA11.No.21-10305.D.E.34 at 20, because no order could be final unless it "dismiss[ed] the *entire* MPIC." CA11.No.21-10305D.E.18 at 18 (emphasis added).

Beyond that, an order dismissing a claim in the MPIC either dismissed a claim in a particular case or it did not. If it did—not due to incorporation by reference, but because the MPIC *was* their pleading—that simply proves that hundreds of people had the same claim in the same pleading, and so were merged. If it did not dismiss *any* claim by *anyone*, then the putative order is merely advisory. Brand Defendants try to repackage "advisory" as the more attractive sounding "important step" along the way to a judgment, Brand.Br. at 51, but Rule 12 does not authorize "important steps" toward disposing of claims. Rather, such motions are to dismiss claims, fully, if they are legally defective. On the Brands' telling, a district court could request 12(b)(6) briefing on the abstract question of whether any plaintiff would be on inquiry notice to sue for injuries related to Zantac by September, 2019, for statute of limitations purposes. It could then *grant* the motion, but announce it is only an "important step" in the resolution of *some* claim *sometime* (for example, people who sued after September, 2021 in states with two-year statutes of limitations). The district court could then delay appellate review indefinitely by not "applying" the ruling to any case filed after September, 2021, circumventing the 150-day clock in

Federal Rule of Civil Procedure 58(c)(2)(B). Worse, the court could put coercive pressure on litigants to default (losing their appellate rights) by requiring them to proceed through expensive discovery and retain experts on their doomed claims—in fact, *that is exactly what the district court did below*, to Mr. Cartee. Even though his short-form complaint merely incorporated a claim in the MPIC by reference that the district court had held was categorically unavailable *on a Rule 12 motion*, the district court claimed it had not "ruled on the legal sufficiency" of his *incorporation by reference*. MDL.Dkt.6317 at 1.

As for the examples of individuality in the cases—a filing fee and a separate docket—these all occurred *before* the cases were merged. Plaintiffs filed individual complaints on an individual docket; but then, they were *required* to file short-form complaints and adopted the MPIC as their operative pleading, superseding their individual complaint and merging their case. At that point, the Clerk stayed each case and prohibited filing anything on the individual dockets. The ultimate entry of judgment on that largely barren docket does not show the cases were meaningfully distinct. Brand.Br. at 48.

The district court's application of summary judgment to later Plaintiffs who were merged into the MDL further confirms that the cases were merged. It deemed the ten general causation experts for the bellwether Plaintiffs to be "The Plaintiffs[']" experts as a whole. MDL.Dkt.6303 at 19-20. It said that "law of the case" applied.

MDL.Dkt.6444 at 10. And, most important, it gave no Plaintiff the opportunity to submit his own expert, *even though Plaintiffs expressly requested such an opportunity*. The Brand Defendants' have no *legal* defense of what the district court did—rather, they stake their entire argument on the factual claim that the district court *did* allow Plaintiffs to submit their own experts. Brand.Br. at 120. The Court can easily check for itself if that assertion is true.

The place to start is the Order to Show Cause. MDL.Dkt.6444. The Brand Defendants represent that this order gave "the precise process [Plaintiffs] asked for," an opportunity for a Plaintiff to disclose "his or her own expert evidence." Brand.Br. at 118 (citing MDL.Dkt.6444). In reality, the order requested "briefing," and strongly telegraphed the Court's own view by stating "five salient points: (1) the case management structure of this MDL always provided for the Court's general causation rulings to apply to all of the Plaintiffs' cases; (2) the theoretical capability of ranitidine to cause cancer is the same across all Defendants and across all cases; (3) the Court's application of its general causation ruling to all of the Plaintiffs' cases should come as no surprise to the Plaintiffs; (4) the Court's ruling applies equally to both the Defendants and to the Plaintiffs; and (5) the Court's ruling results in efficiency and streamlines case management of the MDL." MDL.Dkt.6444 at 8.

In explicating these five points, the court made clear that it believed the cases were merged, and that the factual record and expert designations applied to "all of

the Plaintiffs' cases." The court understood that its "ruling *on general causation* was on the *Plaintiffs'* evidence in support of the proposition that the ranitidine molecule is capable of causing cancer" and that question "is the same no matter where [ranitidine] is found and no matter which Plaintiff's case is implicated." *Id.* at 9 (emphasis added). It waxed eloquent that "applying the court's general causation ruling across all personal injury cases serves the purpose of MDLs." *Id.* at 11 (capitalization normalized).

Last, it requested "responsive briefing to the order to show cause." *Id.* at 13 (capitalization normalized). The briefing was to cover "(i) whether the Plaintiffs **have been afforded due process**, (ii) whether the Court's *Daubert* ruling **was correct**, and (iii) whether the Court's *Daubert* ruling (and related summary judgment ruling) **applies** to certain individual cases." *Id.* With respect to the third issue, the court stated that every "case in this MDL" is bound by "the same pleadings and the same evidence that gave rise to the Court's *Daubert* decision." *Id.* at 14. It added that if any party "argues that a Plaintiff should have the opportunity to relitigate general causation" that party must "provide examples" of that occurring in other MDLs. *Id.* at 15.

Most importantly, for merger purposes, the court asked the parties to brief "law of the case." *Id.* at 16. Specifically, "the parties must address how the law of the case could be different for any individual" and how "the Court [could] reach[]

one conclusion on general causation for earlier-filed Plaintiffs who appeal to the Eleventh Circuit, but reach[] a different general causation conclusion for later-filed Plaintiffs who relitigated the issue." *Id.* This question is nonsensical if the cases were not merged; courts routinely admit certain experts to prove general causation in one case, but exclude other experts proffered to prove the same thing in other cases.

The response to this show cause order was to be a brief "limited to thirty pages." *Id.* at 17. Individual plaintiffs could submit their own brief a few days later on May 5 if they disagreed with Plaintiffs' leadership but would need to comply with the "requirement to address certain topics" identified by the Court. *Id.* at 16-17. This order quite obviously *did not authorize* any plaintiff to submit his own expert report. Plaintiffs' response brief addressed the topics on which the court requested briefing. It objected that "there is no indication that every Plaintiff has consented to using the slate of experts proffered by MDL Plaintiffs' leadership—in fact, certain counsel have strongly indicated they do not wish to do so." MDL.Dkt.6540 at 2. No plaintiff even had *notice* that the leadership slate of experts (which were intended to be used in bellwether cases) would be *her expert*. That is why other "MDL courts provide an opt-out (or opt-in) process," but the lower court never did so. *Id.* at 2. Plaintiffs cited numerous MDLs that used procedures to safeguard due process—providing a deadline for expert disclosures (or adopting leadership's slate); allowing

individual plaintiffs to submit their own experts even after *Daubert*, and so forth. Reading through the response, this Court can have no doubt that Appellants argued full-throatedly that the district court should allow later-filing plaintiffs to disclose their own experts.[3]

After considering those arguments, the district court rejected all of them and entered judgment *without* allowing any plaintiff to proffer his own expert. MDL.Dkt.6622. Incredibly, it then claimed the show-cause process was over and had been conducted "as Plaintiffs' leadership requested." *Id.* at 6. This is preposterous. Requiring briefing on whether to allow a plaintiff to proffer his own expert is not the same as *actually* allowing plaintiffs to proffer his own expert. The latter *demonstrably* never occurred, and the Brand Defendants' representation to the contrary is shameful.[4]

C. Because the Cases Merged, Diversity Jurisdiction Is Lacking.

The cases were merged, which means that parties on both sides of the case were from the same state hundreds of times over. Without complete diversity, the

[3] The response also disputes many of the district court's factual statements, for example about what plaintiffs had previously conceded. *See* MDL.Dkt.6540 at 8.

[4] Under similar circumstances, undersigned counsel *has* proffered experts for individual plaintiffs even after leadership experts were excluded and would have done so here had the district court permitted it. *See*, *e.g.*, Dan McKay, *Judge Seeks Briefing on New Expert Proposed in Tylenol MDL* (Feb. 16, 2024), https://www.law360.com/articles/1803870/judge-seeks-briefing-on-new-expert-proposed-in-tylenol-mdl.

district court lacked jurisdiction, which requires this Court to vacate the judgments and dismiss without prejudice.

Seeking to avoid this result, the Brand Defendants reprise their argument that the cases can be merged for *appellate* purposes but not for *diversity* purposes. Utter nonsense. The notion that "merger" of many actions into one need not have any real consequences *other than* appellate jurisdiction is false. In *Hall v. Hall*, the Supreme Court treats merger as a master concept with transubstantive implications. 584 U.S. 59 (2018). That is why the difference between merger and consolidation controlled "the number of peremptory juror challenges to which each defendant was entitled." *Id.* at 69. Consolidation "does not merge the suits into a single cause, or … make those who are parties in one suit parties in another"—but merger *does* do those things. *Id.* at 70 (quoting *Johnson v. Manhattan Ry. Co.*, 289 U.S. 479, 497 (1933)). Consolidation "does not result in actually making such parties defendants or interveners in the other suit"—only merger does that. *Id.* at 71 (quoting *Adler v. Seaman*, 266 F. 828, 838 (8th Cir. 1920)).

Consolidation does not remove the need for "each constituent case [to] be analyzed individually on appeal to ascertain jurisdiction and to decide its disposition—a compartmentalized analysis that would be gratuitous *if the cases had merged into a single case* subject to a single appeal." *Id.* at 72 (emphasis added). Where cases *are* merged into a single case, jurisdiction is assessed for the case as a

whole. For diversity jurisdiction, that requires examining whether there is complete diversity, considering *all* the parties.

Brand Defendants' proposed remedies would not avoid the need to vacate the judgment. Though the Court can—sparingly—dismiss dispensable non-diverse parties on appeal, there is no precedent for completely unwinding a *merger*, especially where the district court prejudiced plaintiffs so profoundly by treating the record and expert witnesses as the same in every case *because* of the merger. There is no way to give Mr. Cartee back his appeal either. Brand Defendants make much of what Appellants "previously acknowledged" was possible, but that statement was in June 2022, with respect to certain generic cases (but no cases involving Brand Defendants), at a much earlier procedural posture where it was *still possible* to treat each case as individual. In any event, those Appellants were operating on the assumption that the district court's orders dismissed the claims in their case directly, and they could immediately appeal (which is why they were before this Court in 2022). That ship has sailed, and prejudice has built up due to the district court's actions in the meantime. The same remedy is not available now.

Last, Defendants all argue that dismissing for lack of subject-matter jurisdiction would be harmful to MDL litigation. Naked appeals to policy cannot enlarge a federal court's subject-matter jurisdiction. And the policy argument is overwrought in all events. Transferee courts have many ways to avoid merger. To

be sure, when this Court vacates, transferee courts will have less leeway to merge cases so it can apply orders excluding experts in one case to different cases altogether. But that chastisement is long overdue and protecting the rights of individual litigants is a feature not a bug that is hard-coded into our civil justice system. *See In re Nat'l Prescription Opiate Litig.*, 956 F.3d at 845 (warning that even in MDLs, the "decision whether to grant a motion" in one "case depends on the record in that case and not others").

II. The District Court's Preemption Rulings Were Erroneous.

As the Generic-Only opening and reply briefs explain, the district court erred in dismissing claims on preemption grounds. Those briefs are incorporated here by reference. The Defendant groups make various forfeiture arguments or contend that their dismissals can stand on different grounds, but none succeed.

A. The Claims Against the Generic Defendants Survive Preemption.

Appellants incorporation by reference was proper. Against the Generic-Only Appellants' wishes, all of these appeals were consolidated, with the same briefing schedule and oral argument. *See* CA11.No.21-12618.D.E.355. After receiving that order, Appellants structured the arguments to address each distinct topic once to avoid copied-and-pasted arguments. That course was guided by Federal Rule of Appellate Procedure 28(i), which permits adopting "by reference a part of another's brief" and applies to "consolidated cases." Defendants suggest that incorporation is

permitted only within the same *docket*, but Rule 28(i) says nothing about dockets—it refers to "consolidated cases." Since the Court consolidated all Zantac appeals, Appellants believed this was not only helpful to the Court, but also permitted.

If the Court did not intend to allow this, Appellants would note that ignoring the arguments as a sanction would be too severe a penalty, since the Defendants suffered no prejudice. They received, collectively, three times the briefing space. The appeal should be decided on its merits, not on a technical parsing of the consolidation order.[5]

B. The Claims Against the Distributor and Retailer Defendants Survive Preemption.

The Distributor Defendants also object to Appellants' incorporation by reference, but it was proper for the same reasons. Distributor Defendants analogize their objection to *Four Seasons Hotels & Resorts, B.V. v. Consorcio Barr S.A.*, 377 F.3d 1164, 1167 (11th Cir. 2004), but there the party purported to incorporate arguments in its *district court* briefing. Similarly, in *United States v. Schultz*, 565 F.3d 1353, 1362 (11th Cir. 2009), the litigant attempted to adopt arguments in

[5] At risk of prompting another round of complaints, Appellants note that the Class Plaintiffs' Reply Brief addresses the propriety of Appellants' incorporation by reference choices in greater depth in section III.A. The gist is that judicial estoppel does not apply because the representations are consistent, and the Court rejected Appellants' plan anyway.

another appeal that was *not* consolidated. Both are obviously different from incorporating within consolidated cases to avoid repetition, as the Rules allow.

1. Appellants challenged every holding that could support the judgment.

Next, the Distributor Defendants argue that the preemption arguments in the Generic-Only brief do not address certain issues. The preemption arguments the Distributor Defendants flag are either preserved or not genuinely alternative holdings. The district court's order on preemption as to the Distributors and Retailers expressly references and incorporates the order as to the Generics, and the logic is identical. *E.g.*, MDL.Dkt.2513 at 2 n.2. The district court summarizes Plaintiffs' argument to be that "their claims are parallel with federal law—there is no conflict (and therefore no pre-emption) with federal law." *Id.* at 8. It then rejects that argument. It was wrong to do so for the same reasons it was wrong to reject the same argument as to the Generic Defendants.

The purported differences the Distributor Defendants raise are illusory. They argue that the district court *assumed* that state and federal law were parallel "*solely in connection with the district court's order concerning the Generics*." Distributor.Br. at 59. This fact is immaterial. Appellants' preemption argument does not rely on the district court's assumption; rather, it affirmatively explains *why* the duties are parallel. It is true that the district court *stated* the following: "The Plaintiffs' argument that federal law would require the Defendants to stop selling

misbranded drugs is of no moment because the Plaintiffs have not plausibly alleged that the Defendants *knew* that the drugs were misbranded or otherwise could have detected the alleged defects in the ranitidine molecule." MDL.Dkt.2513 at 30. This statement has no citations and could not possibly be specific to the Distributors. It might reflect the district court's view that federal law only prohibits the sale of misbranded drugs if a person "*knew* that the drugs were misbranded." It is difficult to understand why the Distributors believe Appellants forfeited any challenge to that error—after all, the brief argues, at length, that "Under federal law, if a drug is misbranded and sold in interstate commerce, the seller or manufacturer violates the law—irrespective of their knowledge or level of care." Generic-Only Appellants' Op.Br. at 11.

Next, the Distributor Defendants argue that since the district court noted that misbranding claims are only available for "pure design-defect claims" and these "could only be brought against a manufacturer," the claims would fail even if preemption could be defeated against manufacturers. Distributor.Br. at 60 (quotation marks omitted). Neither the Distributor nor Retailer briefing said anything about pure design-defect claims applying only to manufacturers. *See* MDL.Dkt.1583, 1584. The district court's statement was offhand, relating to something that no party argued, and plainly erroneous, since every first-year law

student learns that strict liability claims for design defects (or any other defect) apply to manufacturers, distributors, and retailers alike.

That said, Appellants did not need to challenge this mistake to prevail. The nomenclature of a "pure design-defect claim" is confused and confusing, and Appellants have never adopted it. Two Illinois cases illustrate why. First, consider *Guvenoz v. Target Corp.* where an Illinois court of appeals upheld a panoply of claims against Target (a retailer) rooted in the sale of an unsafe generic drug. *See* 30 N.E.3d 404 (Ill.App. 1 Dist., 2015). None of the claims were "pure design defect" claims—that is not terminology that Illinois courts ever use. But the court of appeals had no trouble recognizing a claim against a retailer that the drug was too unsafe to be sold at all, because there was "no group of patients for whom the drug's benefits outweighed its risks." *Id.* at 419. It upheld multiple state-law causes of action under that general theory, including negligence, negligent misrepresentation, and strict products liability.

Next, consider the case the district court cites, *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices & Products Liability Litigation*, No. 3:09-md-02100, 2015 WL 7272766, at *4 (S.D. Ill. Nov. 18, 2015). The district court represented that the case holds that "the plaintiff could not "assert a 'pure' design defect claim under Illinois law." MDL.Dkt.2513 at 30; *see also* Distributor.Br. at 60 (citing this). *Yasmin* and *Guvenoz* need not be in conflict—it

may be true that Illinois does not recognize "pure design-defect" claims, but it *certainly* is true that it recognizes the "stop-selling" claims in *Guvenoz*. Appellants have argued that the claims in cases like *Guvenoz* are parallel to federal law when federal law would also require a defendant to stop selling. Given that, there is no need to demonstrate anything about the nature of a pure design defect claim. Nothing turns on that question.

Even if the Court held that Appellants forfeited design-defect claims generally, that would not support the judgment because there are multiple non-design-defect claims in the MPIC.

2. Distributors' arguments do not support preemption.

Most of the Distributors' arguments overlap with points made by the Generic Defendants, and to that extent are dealt with by the Generic-Only Reply brief. Some arguments have a new twist.

The Distributor Defendants present a flawed preemption syllogism. First, that state law requires showing that "something was wrong with ranitidine's design or label." Distributor.Br. at 67 (quoting MDL.Dkt.2513 at 23). Second, "that the Retailers and Distributors are 'powerless to cure a design defect in a drug, to make changes to the drug's label, or to issue other warnings without FDA approval.'" *Id.* (quoting MDL.Dkt.2513 at 27). Third, that where federal law bars "'taking the remedial action required to avoid liability,'" there is preemption. *Id.* at 68 (quoting

Bartlett, 570 U.S. at 486). The problem with this argument is not the premises, but the link between them. It works well enough when the state law duty is to change the label. But when, as with ranitidine, a product cannot be made safe, a duty to stop selling arises—note, a *duty* to stop selling, not merely an *option*. Under that circumstance, there is no "remedial action" required by state law, or certainly not one barred by federal law, and so no preemption.

The Distributor Defendants misconstrue this argument later in their brief. While it is true in *general* that whether a drug is "unreasonably dangerous" is "judged in light of the products' warnings and instructions," *id.* at 70, Appellants are not suggesting that their misbranding argument extends to products that would be *made safe* by a warning change. If changing the warning would make the product safe (as was true in *Mensing* and *Bartlett*), the *federal law* duty would be to "ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 616 (2011). In that circumstance, a claim would not be parallel because "[s]tate law demand[s] a safer label; it did not instruct the [m]anufacturers to communicate with the FDA about the possibility of a safer label." *Id.* at 619.[6] A parallel claim would arise only

[6] The same is true under state law. If changing the warning would make a product safe, no state would *require* a defendant to stop selling (rather, it would require an adequate warning). To stop selling would merely be an option, as it was in *Bartlett*.

in the "rare case in which state or federal law actually requires a product to be pulled from the market." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 487 n.3 (2013). That means not only that the drug is unreasonably dangerous in light of its warnings and instructions, but also that changing the warnings would not make it safe.[7]

Similar logic explains the problem with the Distributor Defendants' out-of-context quotation of the "state-law duties." Distributor.Br. at 70. They characterize Appellants' argument as requiring only the *option* to stop selling, based on the quotation that "every state would allow a company to comply with state law by withdrawing the drug from the market." *Id.* at 70 (quoting Generic-Only Op.Br. at 36-37). The Distributors say this is just like *Bartlett*, but the key difference is which law is requiring the market withdrawal. In *Bartlett*, federal law *did not* require market withdrawal, but state law allowed it as one option. In the situation quoted above, federal law *does* require market withdrawal, and the state law either requires it too (a parallel claim) or allows it (a narrower claim). Cases like *Bates* and *Carson* teach that a narrower claim survives preemption the same as a parallel claim. If federal law is *more* protective, and so imposes an *absolute* duty to stop selling, it does not preempt narrower state law that *allows* compliance through cessation.

[7] That is why Distributor Defendants are wrong to say that claims are parallel when the "state and federal law" impose a duty that "might in theory be met either by changing a product's composition or label, or by not selling it at all." Distributor Br. at 71. If the federal duty can be met by changing the label, *Mensing* would apply.

The Distributor Defendants warn that preemption doctrine will be undone if Appellants prevail because "the plaintiffs in nearly *any* drug-defect case can argue . . . that the drugs at issue were dangerous to health when used in accordance with the drug labels." Distributor.Br. at 74. That sky-is-falling resort to policy does not control and is misguided in any event. It is difficult to allege facts that make a federal duty to stop-selling (rather than changing the label) plausible. The obvious question in the typical case would be, "if selling this drug is illegal under federal law, why does the FDA still allow it to be sold?" Here, the FDA itself ordered the recall, which makes the allegations that federal law required Defendants to stop selling quite plausible.

The Distributor Defendants suggest that the federal misbranding statute requires them to have *knowledge* of why a drug is unsafe, but that unsupported contention flouts binding Supreme Court precedent. The lack of any *mens rea* requirement for FDCA misbranding violations has been well-established for decades. *See United States v. Dotterweich*, 320 U.S. 277, 281 (1943). Even a *negligent* state of mind is not required *for criminal* sanctions to attach. *Id.* Distributor Defendants do not cite or distinguish *Dotterweich* (which was in the opening brief). Rather, they suggest that this "knowledge" requirement comes from *Bartlett*, but *Bartlett* obviously never says a *defendant* would need to know new information. Rather, it notes that liability must be "based on new and scientifically

significant information that was not *before the FDA*." *Bartlett*, 570 U.S. at 487 n.4 (emphasis added).[8] The point of that caution is to avoid second-guessing safety risks that the FDA already considered during approval of the drug. The logic goes that if the FDA already considered the exact risk at issue and did *not* recall the drug, then it probably complies with federal law. Thus, plaintiffs need to plead that information arose concerning a risk that the FDA did not consider during approval (such as NDMA in ranitidine). None of this requires a defendant to know anything.

The Distributor Defendants raise the possibility of a "good faith" defense to penalties under the federal misbranding statute but cannot show it exists or would matter if it did. Distributor.Br. at 92. The defense in 21 U.S.C. §333(c) is a defense to "the penalties of subsection (a)(1) of this section," which are *criminal* penalties, authorizing prison time. *See* 21 U.S.C. §333(a)(1). Section 333(c) is not a defense against civil enforcement of any kind. Beyond that, the defense applies to "having received … and delivered" or "proffered delivery" of a drug, which maps onto 21 U.S.C. §331(c). ("The receipt in interstate commerce of any … drug … that is adulterated or misbranded, and the delivery or proffered delivery therof for pay"). Appellants need not rely on section 331(c), because Distributors did not merely

[8] The Distributor Defendants cite an amicus brief from the United States which sometimes mentions a defendants' knowledge. Distributor Br. at 81. The Supreme Court declined to include this language, suggesting it rejected it.

receive and *deliver* ranitidine, but also resold it to retailers and consumers. Thus, they violated section 331(a), which covers the "introduction … into interstate commerce" of a misbranded drug. And they violated section 331(b), which covers the "adulteration" of drugs, which they performed by causing NDMA to build up in ranitidine while they possessed it.

Even if the defense fully barred any penalty—which it does not—preemption, and parallel claims jurisprudence, are about comparing the *duties* under federal and state law, not the *remedies* for breach of those duties. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *id.* at 513 (O'Connor, J., concurring). If federal and state law impose the exact same duty, it is irrelevant for preemption purposes that the federal sovereign may be content with a slap on the wrist while the state sovereign requires full compensation to an injured victim. *Id.* The Distributor Defendants cannot (and do not) cite a single case to the contrary.

C. The Claims Against the Brand Defendants Survive Preemption.

The Brand Defendants argue that Plaintiffs forfeited their preemption arguments but are light on the details. The district court expressly rested its first preemption ruling with respect to the Brand Defendants on the analysis in the order addressing the Generic Defendants. *See* MDL.Dkt.2532 at 24 (referring the reader to the generic order, which "discusses the Plaintiffs' misbranding theory at length").

For the second preemption order (addressing *Buckman* preemption), the court flipped the order, applying preemption in the brand order, MDL.Dkt.3715, and then incorporating it by reference in the generic order, *see* MDL.Dkt.3750 at 23 (applying preemption for "the same reasons given in that Order"). Given that the district court simply incorporated its own rulings, it is hardly surprising that Appellants' arguments are the same with respect to all Defendants.

The Brand Defendants' arguments about misbranding do not appear to contain any new arguments. Appellants refer the Court to the Generic-Only Reply.

With respect to Count V (failure-to-warn-through-the-FDA), the Brand Defendants assert that the claim is "based on alleged failure to submit annual reports and adverse event reports to FDA as required by *federal* regulations." Brand.Br. at 133. That is incomplete. The claim encompasses adverse event reports, *see* AMPIC¶¶1390-91, but it also includes a failure to send "new analyses of data, newly revealed risks" and "new testing." AMPIC¶1392; *see also* AMPIC¶1412 ("Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting."). For example, GSK failed to send the Tanner study; all Defendants failed to relay information about ranitidine's cancer risk (including their own cancer

studies); and, as a result, the FDA, a third-party intermediary, could not tell consumers about the risks. AMPIC¶¶1399-1401.

Brand Defendants suggest that there is a preemption problem under *Mensing* because the claim depends on "uncertain and discretionary FDA actions," but Brand Defendants are simply ignoring the nature of the state-law duty. Brand.Br. at 134. The key difference between this claim and a normal failure to warn claim (like that in *Mensing*), is that the state-law duty is *fully satisfied* by sending along the information to the FDA—no matter what the FDA does next. Thus, it can be satisfied *unilaterally* by the Defendants. The discretionary action of FDA, *i.e.* would it have acted sooner to pull ranitidine from the market, preventing Plaintiffs' injuries, is relevant only to *causation,* not breach of duty. And the Supreme Court has long held that additional state-law elements alongside a breach of parallel duties, which make it *harder* for plaintiff to recover, do not implicate preemption. *Lohr*, 518 U.S. at 495 ("additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement" which is "a strange reason for finding pre-emption).

D. The District Court Erred in Holding That Impossibility Preemption Bars State-Law Claims in the MPIC That Parallel Federal Law.

All Plaintiffs argued that the claims in the MPIC survived preemption against every category of Defendant to the extent they paralleled federal law. Simply put,

federal law prohibited any Defendant from selling ranitidine, and so federal law does not operate as a shield for their conduct, which violated state *and* federal law. The district court rejected that argument. *See* MDL.Dkt.2512 (Generic Preemption Order), 2513 (Distributor, Retailer, and Pharmacy Preemption Order), 2532 (Brand Preemption Order). As argued in the Generic-Only Appellants' opening brief, the parallel misbranding argument is sound, and the district court's dismissal was erroneous. Appellants incorporate the arguments in that brief by reference, which apply with full force to the other Defendants too.

E. The FDCA Does Not Preempt the Amended Claims Because They Rest on State Law Requirements That Defendants Could Have Fulfilled.

The district court dismissed all claims against the Generic Defendants in the AMPIC on preemption grounds, MDL.Dkt.3750 at 2, 49, and Count V against the Brand Defendants, MDL.Dkt.3715 at 49-50. Appellants incorporate the arguments made in the Generic-Only opening brief, both as to the Generic Defendants, and, with respect to Count V, the Brand Defendants as well.

III. The District Court Erred In Granting Summary Judgment.

Defendants' attempt to paint the Plaintiffs' experts as outliers, but it is the lower court that stands out. Since the district court's *Daubert* opinion was issued, Zantac litigation has continued apace in state courts. Multiple judges in Delaware, Illinois, and California have decided motions to exclude experts under a *Daubert* or

the stricter *Frye* standard. Defendants have cited the lower court's *Daubert* order up and down but have not persuaded even one court to exclude expert testimony about the cancers at issue here.[9] Despite assertions from the Defendants (and district court) that ranitidine *cannot* cause cancer, it is still off the market, both in the United States and in every other country.

Something went badly wrong in this MDL. The due process violations, merger, refusal to allow early appeals, and double-digit alternative holdings in a 300+ page order are not a model for civil litigation. They are a model for stymieing appellate review. Pointing out that the district court relied on a British tabloid and misunderstood basic chemistry is not "[d]isparagement," Brand.Br. at 55[10]—it is

[9] The California JCCP has entered multiple orders on *Sargon/Kelly* Motions in the *In re Ranitidine Products Cases*, No. JCCP 5150 (Cal. Super Ct., Alameda Cnty.), including on Mar. 23, 2023 (Exhibit 1), Aug. 21, 2024 (Exhibit 2), Oct. 24, 2024 (Exhibits 3-6). The Delaware court allowed experts on ten cancers to testify. *In re Zantac (Ranitidine) Litig.*, No. N22C-09-101 ZAN, 2024 WL 2812168 (Del. Super. Ct. June 3, 2024). Illinois courts have permitted multiple experts to testify. *See* Order Memorializing the Court's Rulings from the April 16, 2024 Pre-Trial Hearing, *Valadez v. GlaxoSmithKline LLC*, No. 2023-L-000483 (Ill. Cir. Ct., Cook Cnty. Apr. 25, 2024) (Exhibit 7); Order, *Gross v. GlaxoSmithKline LLC*, No. 2023-L-000469 (Ill. Cir. Ct., Cook Cnty. June 3, 2024) (Exhibit 8); Order, *Kimbrow v. Walgreen Co.*, No. 2023-L-005405 (Ill. Cir. Ct., Cook Cnty. July 17, 2024) (Exhibit 9); Order, *Dixon v. Walgreen Co.*, No. 2023-L-001427 (Ill. Cir. Ct., Cook Cnty. Sept. 5, 2024) (Exhibit 10).

[10] Brand Defendants attempt to defend the district court's flub by noting that sodium nitrite is, technically "*a* salt." Brand Br. at 56 n.19 (emphasis added). The district court did not call sodium nitrite "a salt," but simply "salt"—more than ten times. It would hardly be surprising that the court confused these two similar-sounding

necessary context to underscore what happens when a court arrogates factfinding powers to itself under the guise of assessing methodological reliability. No one can read the lower court's *Daubert* order without suspecting that its length is not entirely a function of thoroughness.

A. The District Court Misapplied *McClain*.

NDMA is widely recognized to cause cancer, and so fits within *McClain* category 1. Defendants argue that the district court properly focused on *ranitidine*, not NDMA, because "Plaintiffs did not ingest NDMA molecules by themselves; they ingested ranitidine," Brand.Br. at 59, but no one ingests archetypal category 1 substances like asbestos, arsenic, or alcohol in pure form either. The opening brief analogized alcohol to NDMA. Alcohol is in category 1. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 n.5 (11th Cir. 2005). But people *ingest* alcohol in beer, cocktails, and so forth. That a category 1 toxin is consumed within a product with other ingredients such as hops or water does not take it outside category 1. Defendants have no response. *McClain* category 1 would be dead letter if it only applied when consumers "ingest [the category 1] molecules by themselves." There

chemicals, since it admitted to "perhaps mistakenly, using the words 'nitrate' and 'nitrite' interchangeably." MDL.Dkt.6120 at 157 n.80. To be fair, the attorneys also mixed up terms sometimes. But this only underscores the risks associated with judicial deviations from Rule 702's limited gatekeeping function.

is no medical literature demonstrating that Miller Lite causes cirrhosis of the liver; and never will be, because scientists rely on studies about alcohol.

Brand Defendants claim that treating NDMA as a category 1 substance "would lead to absurd results" because it is in "air, water, and food," but it would be no different from other category 1 substances. Brand.Br. at 62 (quotation marks omitted). Asbestos and cigarette smoke are also in the air; silica (another category 1 substance) is found in most sand; some level of arsenic is in most water. Despite this, no Plaintiffs are suing random defendants because a trace category 1 substance in the "air" harmed them. Presumably this is because plaintiffs know they cannot prove (1) who *put* the substance in the air or water; (2) that doing so was negligent; (3) that the exposure caused the plaintiff's specific injury. The Court should reject Defendants' Chicken Little arguments out of hand.

B. The District Court Erred in Applying this Court's Primary Methodology Test.

Plaintiffs' experts in these appeals were among the most qualified scientists and doctors in their fields. They wrote careful reports considering the background rates of the relevant diseases, all available epidemiology, and dose-response data (not to mention a host of other evidence). This is not a case about an expert who failed to assess something. The experts covered every angle—the district court simply did not agree with their conclusions. That is not a ground for exclusion under *Daubert*.

1. The experts reliably employed studies showing background risk.

This Court counts background risk as a primary methodology, and Plaintiffs' experts *did* examine background risk and the *increase* in risk associated with ranitidine. *See, e.g.*, MDL.Dkt.6171-9 at 18 (McTiernan); MDL.Dkt.6179-6 at 65 (Moorman). Just last month, this Court reaffirmed that background risk of disease simply means "'the risk . . . the general public ha[s] of suffering the disease or injury that [a] plaintiff alleges *without exposure to the drug or chemical in question*.'" *In re Deepwater Horizon BELO Cases*, 119 F.4th 937, 941 (11th Cir. 2024) (alterations and omission in original) (quoting *McClain*, 401 F.3d at 1243). Every user / non-user epidemiology study design did exactly this, since a "non-user" is, by definition someone "without exposure to the drug." *Id.*

In response, Brand Defendants implausibly assert that "the experts *ignored* background risk by favoring non-user comparisons over active-comparator analyses." Brand.Br. at 110. Brand Defendants cite no authority—medical or legal—for the proposition that "background risk" means "the risk of people taking a similar class of drug." This Court has consistently defined it as people *not* taking the drug. Brand Defendants provide no other response to the studies and increased risk cited in the opening brief. *See* Appellants' Op.Br. at 42 & n.18.

2. The experts reliably employed epidemiology studies.

The experts undisputedly used standard, accepted methodologies in assessing epidemiology. For example, Dr. McTiernan (who has both an M.D. and Ph.D. in epidemiology) has performed causal evaluations for the International Agency for Research on Cancer, MDL.Dkt.6185-15 (McTiernan Dep. Tr.) at 680, and used the same methodology here. She performed a comprehensive epidemiology literature review, MDL.Dkt.6171-9 at 98-110, described the strengths and weaknesses of cohort, case-control, meta-analysis, and other study designs, *id.* at 38-48, and then evaluated every study in detail, exhaustively listing biases and confounding factors, *id.* at 49-70, and strengths and weaknesses, *id.* at 103-10 (assessing study size, exposure duration, exposure frequency, OTC usage information, the age of the participants, method and reliability of outcome measurement, accuracy of the determination of exposure, accuracy of the determination of cancer, data accuracy, and whether populations are well characterized so that confounding variables can be accounted for). Her extensive report included charts that summarized every relevant study. There is simply no question that she examined epidemiology as this Court requires.

Defendants nonetheless defend the exclusion of each expert because they purportedly "reach[] a conclusion that other experts in the field would not reach." Brand.Br. at 65-66 (quotation marks omitted). This argument ignores the worldwide

consensus that ranitidine is *too dangerous to sell at all* because it contains NDMA, a carcinogen. The *only* people in the world saying ranitidine is *safe* are the Defendants and their paid experts. It is true that other "experts in the field" have not yet opined that ranitidine causes cancer—but nobody has looked. A *causal* analysis is customarily done by IARC, ATSDR, or other organizations that collect *all* the evidence and then carefully review and analyze it over hundreds of pages. These take years. Defendants point to *no* actual causal analyses by any scientist, much less one that concludes ranitidine does not cause cancer. The various epidemiology studies of short-term Zantac use are less than 20 pages, and do not review anything close to all the evidence that would be necessary to assess causation. That such papers do not opine one way or the other on causation does not suggest that Plaintiffs' experts have deployed unreliable methods or reached unsupported conclusions.

3. The experts reliably employed studies showing dose-response.

Essentially the *only* responsive point Defendants make is the generic argument that "Dr. Salmon ignored statistical significance and confounding when selecting data from Cardwell and Wang, even though he agrees with the importance of those scientific concepts." Brand.Br. at 106. Every expert will agree with the "importance of the concept" of confounding, and here, the "confounding" Defendants worry about is the *possibility* that Cardwell's primary analysis (versus

non-users) *and* one of his sensitivity analyses (versus PPIs) are confounded by smoking. Cardwell did not believe that was a problem, took steps to control for smoking, and reported that the study *supported* dose-response. Surely Dr. Salmon can agree and let the jury decide. As for Wang, Defendants have no response whatsoever to the dose-response finding for liver cancer, training their fire only on gastric cancer. *Id.* Dr. Salmon can testify about a "trend" in the dose response data for gastric cancer, but even if he could not, surely he can testify about the *finding* of dose-response for liver cancer.

The Court recently clarified that threshold dose is relevant to general causation, not only specific causation. *In re Deepwater Horizon*, 119 F.4th at 945-46. Still, the Court has always treated dose-response as a toxicology principle, and, in *Deepwater Horizon*, it reserved the question of whether threshold dose is required for epidemiology. *Id.* at 946-47. As the opening brief argued—and Defendants do not dispute—Bradford Hill analysis does not require identifying a threshold dose: even dose-response is only one of nine Hill criteria, and scientists routinely find causation after a Bradford Hill analysis even if dose response is not found. The Court should not answer the question it left open by holding that the way actual epidemiologists practice their discipline in the laboratory is methodologically unreliable in a courtroom. Indeed, the reason epidemiology is a *separate* primary methodology from threshold dose is because it offers a long-accepted, alternative

way that scientists draw a causal inference. Plaintiffs' epidemiologists sufficiently surmounted the threshold dose requirement by using epidemiology, including both ranitidine studies (like Wang and Cardwell), and NDMA epidemiology (such as Hidajat and dietary studies), all of which showed not only increased risk, but dose-response.[11] Because the studies *found* a risk, the doses in the study must have been above the threshold dose, by definition.

C. The District Court Improperly Took Sides in a Scientific Debate.

In its ever-growing list of alternative holdings, the district court strayed over multiple areas of scientific dispute, taking sides in the debate and declaring the other side unreliable. That was error.

First, the district court misunderstood the role of epidemiological studies, insisting that if a study did not *affirmatively conclude* that ranitidine causes cancer, then Plaintiffs' experts could not rely on it in drawing an overall inference of causation. Defendants reprise that argument, stating that "no study *has concluded* that ranitidine use can cause cancer." Brand.Br. at 86 (emphasis added). The scientific community uses either randomized controlled trials or a Bradford Hill analysis to come to conclusions about causation. It is undisputed that *none* of the

[11] Defendants spend considerable time addressing Dr. Najafi's testing, but Appellants have not appealed that exclusion, largely because it was partly based on "integration" errors (processing errors). It is notable that in subsequent litigation, Dr. Najafi re-processed all his testing, which did not substantially change the numbers, and that re-processed testing has uniformly been admitted.

studies that have been conducted—anywhere—have used either of these methodologies. IARC has not examined ranitidine, for example, to discern whether it can cause cancer. Rather, the studies at issue are the raw materials scientists would analyze. These types of observational studies *never* draw conclusions about causation, because the methodology they employ—looking for associations from population comparisons—is not capable of determining causation. If any of the epidemiological articles announced they had identified a *causal* association, that would have been a reason to question the author's bona fides.

Simply put, no one believes an inference of causation would be appropriate on the basis of a single epidemiological study—that requires a full review of the evidence and Bradford Hill analysis. If the requirement in this Circuit becomes a demand that epidemiological studies find causation before an expert can infer causation using Bradford Hill, general causation experts will always be excluded, and this Court will have announced a rule of law that defies how scientists actually practice their disciplines. That turns Rule 702 on its head.

Second, Plaintiffs' experts' approach to statistical significance was fully within the mainstream; the district court's demand that they treat *any* association without statistical significance as "biased" was error. Defendants have no response—literally none—to the opening brief's discussion of Professor Rothman's authoritative position on statistical significance, which has been adopted by ATSDR

and is taught in Rothman's celebrated Modern Epidemiology textbook. This is a mainstream view, as evidenced by 834 epidemiologists and statisticians around the world who called for "moving beyond" statistical significance in *Nature*, one of the top scientific journals. *See* Valentine Amrhein, et al., *Scientists Rise Up Against Statistical Significance*, Nature, Mar. 20, 2019.

In any event, the experts emphatically did *not* ignore statistical significance. Every single expert listed confidence intervals for every study's results and took due account of it. For example, Dr. McTiernan's report discusses statistical significance or confidence intervals *literally hundreds of times*. *See generally* MDL.Dkt.6171-9. Defendants suggest that Plaintiffs' experts "disregarded . . . negative results purportedly because the results were not statistically significant" even though they considered positive results, but this claim is not supported by any citation to the record, does not quote any report or deposition testimony, and appears to be made up. Brand.Br. at 23. Every time each expert gave lesser weight to a *decreased* risk, it was because of the study's flaws. For example, the Kim Y. study reported implausible reductions in cancer risk, and Dr. McTiernan identified devastating flaws in the study over multiple pages in her report—she did not simply disregard it based on the lack of statistical significance. MDL.Dkt.6171-9 at 119-22.

Nor were the experts inconsistent. Both Dr. Moorman and Dr. McTiernan have authored a dozens of peer-reviewed articles that *do* describe relative risks above

1.0 as "positive associations" even without statistical significance. *See* MDL.Dkt.5947-5 at 81, n.208-209 (listing and quoting examples). It is not surprising that, among Dr. McTiernan's many hundreds of scientific publications with scores of co-authors, one or two of them discount a result based on statistical significance. It certainly is not a basis for exclusion.

Third, the district court erred in concluding that the *only* reliable evidence showing an increased risk were the H2 blocker active comparator sub-analyses of the various studies. Epidemiologists routinely consider the "main" analysis—which for Cardwell, Wang, and many other studies was the user/non-user analysis—and use the sensitivity analysis as a gut-check. MDL.Dkt.6179-1 at 31-32. As Dr. McTiernan explained, "In epidemiologic studies, sensitivity analyses are secondary analyses, and are not reported as main results." MDL.Dkt.6179-1 at 31-32. The Cardwell study, for example, characterizes the *main* result as the user/non-user finding, then adds: 'Sensitivity analyses. Various additional analyses were conducted, including 2 active comparator analyses.'" MDL.Dkt.6185-31 at 5. The Cardwell study itself summarizes its results as showing that "[u]se of ranitidine was associated with increased bladder cancer risk," because that was the main analysis. *Id.* at 7. Even Defendants' own expert Dr. Vaezi has used user/non-user study designs in assessing the cancer risk of PPIs as recently as 2021, even though an active comparator study design was possible. *See* MDL.Dkt.6179-1 at 14.

Whether to use an active comparator analysis—and how much weight to give it—is within the realm of scientific debate. And contrary to Defendants' suggestion, Dr. McTiernan did discuss "active comparators" in her report—more than twenty times, and even included a chart laying out "Comparators, Doses, Missing Data, and Follow-up," which *did*, contrary to the Brand Defendants' suggestion, flag the Cardwell active comparator sensitivity analysis. MDL.Dkt.6171-9 at 153-56. She did not discount active comparator results *for being active comparator results*, but for independent reasons: "The issue here is not the use of active comparator study types—it is the way the specific studies discussed in my report were designed and conducted." MDL.Dkt.6179-1 at 10. The particular issue depended on the study, which each report laid out in a separate section on "weaknesses" for each and every study.

For example, in Denmark during the study periods for Norgaard and Adami, 80% of ranitidine sales were over-the-counter and *not* covered by social insurance, while all PPIs were by prescription and covered—that was one basis Dr. McTiernan gave for giving less weight to the Norgaard and Adami studies, which compared ranitidine to PPIs without accounting for this serious confounding factor. MDL.Dkt.6171-9 at 128, 185-86. Beyond that, the studies did not control for smoking. *Id.* These critiques are just two of many legitimate critiques. Simply put, Defendants blame Plaintiffs' experts for failing to credit specific studies that *happen*

to be active comparator studies, but do not engage with the reasons the experts gave for their weighting. Defendants' assertion that the weighting was based on disliking active comparator results has no support in the experts' actual opinions. That is also why there is no inconsistency in crediting the Wang study's active comparator analysis—it simply proves the point that Plaintiffs' experts never had any problem with active comparator analyses in general.[12]

Fourth, the district court erred in deeming entire areas of science—occupational and dietary studies—categorically unreliable, despite being relied upon by the FDA, ATSDR, IARC, and other authorities around the world. These studies work by drawing correlations between NDMA intake (estimated based on foods or occupational exposure) and cancer. Contrary to Defendants' arguments, the studies control for exposure to other carcinogens. It is simply not credible that "dietary and occupational studies suffer from *inherent flaws*." Brand.Br. at 96 (emphasis added). The World Health Organization relied on dietary studies in assessing the

[12] As further confirmation that Defendants misunderstand this point, they claim that the critiques of follow-up times "affect the studies as a whole, not just the active-comparator data—and yet the experts relied on those studies' *non*-active-comparator data." Brand Br. at 82. This might be a good point if it were true, but it is not. For example, the Iwagami study had a follow-up period of 2.3 years, which is obviously insufficient and led Dr. McTiernan to deem it "minimally informative." MDL.Dkt.6171-9 at 141. The Yoon study had follow-up of up-to (but on average less than) 7 years, which the authors conceded was "not long enough to assess the onset of cancer," MDL.Dkt.6187-29 at 8, and Dr. McTiernan did not treat any analysis in that study different from any other. The same is true of other studies.

carcinogenicity of NDMA. *See* MDL.Dkt.6159-10 at 20, 26. At minimum, relying on such studies is not categorically unreliable.

Brand Defendants suggest that Dr. McTiernan has cast doubt on case-control studies due to recall bias but omit that she has consistently relied on them despite that potential limitation. *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales & Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 162 (D.N.J. 2020) (summarizing Dr. McTiernan's admissible testimony as relying on 28 case-control studies). Recall bias would be non-differential, biasing the result to the null anyway, which would *understate* the risk. As for Defendants' concerns about the Hidajat study, Dr. Hidajat was a disclosed expert in this case and testified that her study supported Plaintiffs, and that Defendants' concerns were overstated. *See* MDL.Dkt.6171-4. Defendants did not even move to exclude her.

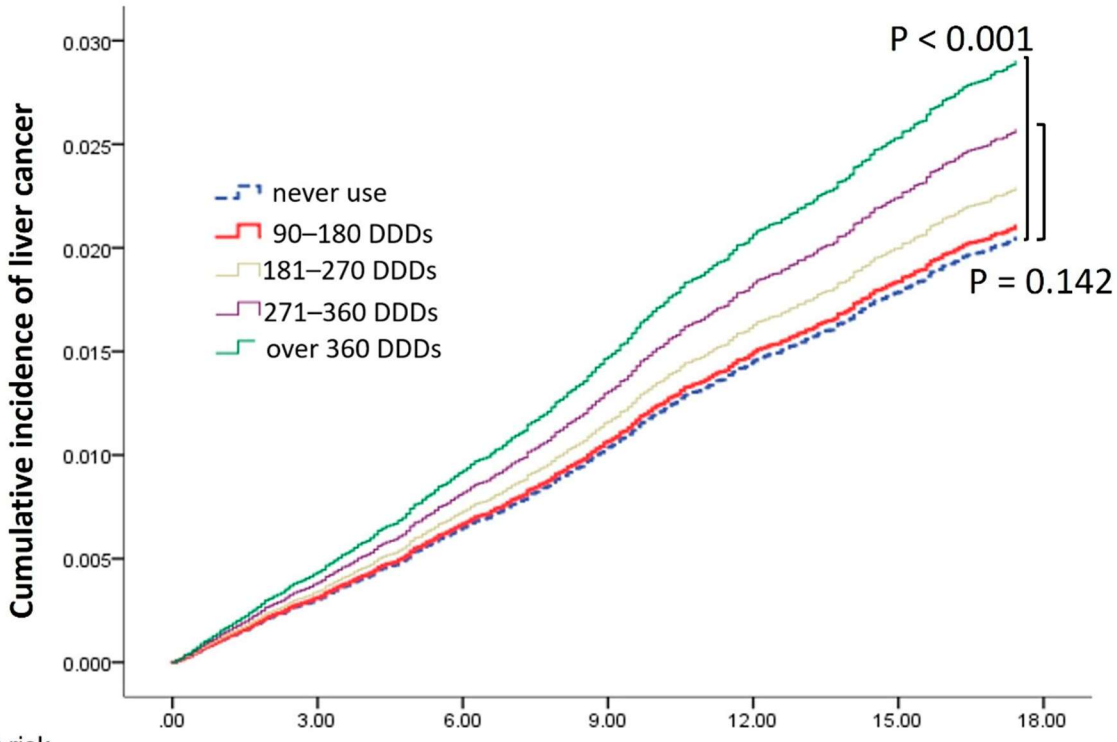
D. The District Court's Myriad "Alternative" Reasons for Excluding Specific Experts Were Misguided.

Incredibly, the Brand Defendants lead by suggesting that Dr. McTiernan's methodology was "'general, brief, and lacking in specificity.'" Brand.Br. at 113 (quoting MDL.Dkt.6120 at 251-52). The report is hundreds of pages long and explains her methodology in exhaustive detail. This Court has affirmed exclusion of an expert's "cursory discussion of the [Bradford] Hill factors" where the expert "addressed only three of the nine factors in a few brief sentences." *In re Deepwater Horizon*, 119 F.4th at 947. This case is the opposite extreme. Dr. McTiernan first

explained the nature of Bradford Hill analysis, explaining each factor at length. MDL.Dkt.6171-9 at 93-98. Then, she explained *at length* for *each cancer* how the factors applied. *E.g.*, *id.* at 201-207 (bladder cancer); *id.* at 220-226 (esophageal cancer); *id.* at 235-39 (liver cancer); *id.* at 252-58 (pancreatic cancer); *id.* at 281-83 (stomach cancer). If *this* is too "general, brief, and lacking in specificity," then *every* Bradford Hill analysis is.

Dr. Moorman's analysis was wholly consistent, as the opening brief explained. It is ridiculous to suggest that Dr. Moorman "disregarded ranitidine active-comparator epidemiology" when her report discussed each and every result. Brand.Br. at 115. To "disregard" means to ignore—that did not happen. Rather, for each study Dr. Moorman gave specific reasons for her weighting. For example, the Kantor study had a follow-up period of 6.7 years and included users who took ranitidine for *four weeks*. MDL.Dkt.6179-6 at 68. Its numbers for ranitidine and omeprazole usage contradicted other sources of information, which suggested problems with the "exposure definition" not capturing most usage. *Id.* at 69. And so, Dr. Moorman gave the study "little weight." *Id.* 70. Notably, she did not give the non-user analysis high weight and the active comparator low weight—the entire study received low weight. Defendants pretend otherwise by ignoring the reports' express discussion of weighting and weaknesses for every study.

Defendants purport to find a "glaring inconsistency" in saying that ranitidine *can* cause cancer with regular exposure for 1-3 years and saying that a short follow-up period will not detect a risk. Brand.Br. at 116. The Brand Defendants' confusion shows their misunderstanding of the concept of exposure and follow-up. Exposure addresses how much ranitidine will cause cancer. Follow-up addresses latency—how long will it take for the cancer to develop. The Wang study illustrates this principle with a Kaplan-Meier graph which plots cancer incidence on the Y axis and years of follow-up on the X axis, and then plots lines in different colors showing exposure. MDL.Dkt.6061-6 at 10. The graph shows lines of different colors corresponding to different exposure amounts (from none to about a year of exposure). It also shows that the *difference between the lines* increases as follow-up increases. After 3 years of follow-up, the lines are essentially indistinguishable. By 18 years, the difference is unmistakable. The highest exposure line (the green one) is still only a year, which is much shorter than the average plaintiff, who consumed ranitidine for ten years.



Num. at risk							
over 360 DDDs	14,787	12,546	9,009	5,733	4,611	3,349	1,098
271–360 DDDs	5,289	4,334	3,316	2,412	1,973	1,472	471
181–270 DDDs	10,844	9,202	7,354	5,668	4,741	3,531	985
90–180 DDDs	24,190	20,098	15,821	12,151	10,162	7,449	2,051
never use	55,110	46,420	36,022	26,605	22,149	16,208	4,754

Last, Defendants claim that treating dietary study follow-up periods differently from ranitidine is "inconsistent," but ignore the differences. Brand.Br. at 115. All the ranitidine studies were *new user* designs, meaning the follow-up periods were the *maximum* time from consumption of the first ranitidine pill until cancer development. By contrast, all human study participants eat food before they enter a dietary study—in fact, their diet is likely identical in terms of NDMA consumption—which means the follow-up periods of dietary studies are functionally much longer, because the exposure pre-existed the commencement of the study.

This Court need not agree with Plaintiffs' experts on any of these points. The district court plainly did not. But the relevant question under Rule 702 is whether the experts' approaches were so methodologically out of step that they constituted junk science or produced conclusions that were entirely divorced from sound scientific predicates. Defendants cannot defend the district court's judgment under that standard. It is indefensible.

IV. The District Court Erred In Dismissing Negligent Misrepresentation Claims By Consumers Of Generic Ranitidine Against Brand Defendants.

The district court's extravagant order holding that there is no duty by Brand Defendants to consumers of generic drugs in any state and that there is no personal jurisdiction cannot stand. Though Brand Defendants claim the Court need not reach any issue if it upholds the *Daubert* order, that is incorrect. The Brand Defendants concede that the negligent misrepresentation claims were *only* "dismissed for lack of personal jurisdiction," and were *not* covered by the "summary-judgment order." Brand.Br. at 154 n.42. Because Brand Defendants now concede dismissal was without prejudice and that there is *no* alternative ground for affirming, the Court must resolve the parties' personal jurisdiction argument, at minimum.

A. The District Court's Personal Jurisdiction Ruling Was Erroneous.

No court before the district court had ever held that negligent misrepresentation claims against Brand Defendants were categorically unavailable

under the Due Process Clause of the Fourteenth Amendment. That grave intrusion on state law must be reversed.

Brand Defendants do not challenge purposeful availment. They cannot, given the extensive allegations in the pleading. *E.g.*, AMPIC ¶¶ 228-33.

They do challenge the "relate to" prong, but do so by ignoring the AMPIC's allegations. Brand Defendants advertised in California and Massachusetts; had sales forces there; had employees there; communicated with doctors there; and in every respect built and cultivated a market *for ranitidine*. It is no surprise that consumers and doctors saw those advertisements, and that doctors prescribed Zantac, and that pharmacists substituted generic ranitidine. The connection between the claim and the forum is palpable—but-for causation is not required, but it is present here.

To see why negligent misrepresentation could not possibly require selling a product, consider an advertising campaign telling consumers to ingest high levels of horse tranquilizer to get a pleasant buzz. If a consumer relied on that representation, bought horse tranquilizer, and was injured by it, he could sue for negligent misrepresentation. It makes no difference whether the purveyor of the negligent misrepresentation *also* sold the horse tranquilizer. The federal constitution simply cannot be stretched to mean that companies are immunized for their misrepresentations about a given substance whenever a plaintiff purchases the substance from some other seller.

Brand Defendants try to elide these facts by stating that "promotion of their own products *has nothing to do with* generic products sold by their competitors," Brand.Br. at 150, but this is factually false. Brand Defendants receive profound benefit from selling their drugs in California and Massachusetts; part of the burdens is facing tort suits for generic products also sold there, which it knew well upon entering the market. Brand Defendants pretend that this case is the same as a case in which they *never entered* California but were held liable anyway. That case is not before this Court, and the theoretical possibility of it occurring in other cases makes no difference to the personal jurisdiction standard this Court should apply. Just as in *Ford v. Montana Eighth Judicial District Court*, it matters that the "place of a plaintiff's injury and residence" are in the forum, since "[t]hose places still may be relevant in assessing the link between the defendant's forum contacts and the plaintiff 's suit—including its assertions of who was injured where" even if there is no *causal* connection to the defendants' actions. 592 U.S. 351, 371 (2021).

B. The Court Should Certify the Question to State Courts.

1. Plaintiffs did not forfeit their request for certification.

This Court has never required parties to request certification in the district court before they can request it in this Court. Defendants purport to find an exception because Plaintiffs intentionally "chose . . . as a matter of litigation strategy" to insist that the district court make *Erie* guesses. Brand.Br. at 138. In

reality, Plaintiffs opposed at every step. Certification to a state supreme court carries gravity and is not to be invoked by parties on every unsettled state law question in district court. Yet, if this Court rules for Defendants, that is exactly what litigants would be required to do, under pain of forfeiting their ability to request for certification later, when the issue is clearer and more developed.

a. This Court has never required requesting certification in the district court.

Requesting certification in the district court has never been required—or even recommended—by this Court. The situation presented here (a district court ruling that is challenged on appeal), matches essentially all of this court's precedents in which a case was certified. In *Pogue v. Oglethorpe Power Corp.*, the district court granted summary judgment, and on appeal, this Court certified the question. 82 F.3d 1012, 1017 (11th Cir. 1996). The same thing happened in myriad other cases. *E.g.*; *CSX Transp., Inc. v. City of Garden City*, 325 F.3d 1236, 1249 (11th Cir. 2003); *Mosher v. Speedstar Div. of AMCA Int'l, Inc.*, 52 F.3d 913, 917 (11th Cir. 1995). This Court has discussed the various factors to be considered in certifying a question and has never said that it matters whether the party requested certification in the district court.

In fact, this Court has said the opposite. Its precedents teach that "certification turns much more on federalism concerns than on timeliness concerns. In fact, a party need not raise the issue at all[.]" *Whiteside v. GEICO Indem. Co.*, 977 F.3d 1014,

1018 (11th Cir. 2020). To be clear, "at all" means "at all"—even raising a certification request for the first time *in a reply brief* does not forfeit the request. *Cordero v. Transamerica Annuity Serv. Corp.*, 34 F.4th 994, 999 (11th Cir. 2022) (citing *Whiteside*, 977 F.3d at 1018). To manufacture a problem, Defendants cite out-of-circuit cases. Most of the cases do not actually require a party to request certification in the district court.[13] And it does not appear that even those circuits *follow* the rule Defendants propose.[14] This Court's precedents control over an inconsistent out-of-circuit rule, especially here, where Plaintiffs had no notice that they would be required to seek certification to avoid forfeiture.

Defendants next argue that this Court should adopt a new rule requiring a certification request in the district court where the plaintiffs affirmatively requested that the court reach the issue as a matter of litigation strategy, but this theory falls flat on the facts.

[13] For example, the Eighth Circuit principally declined "certification because the legal question is neither close nor likely to recur." *Perkins v. Clark Equip. Co., Melrose Div.*, 823 F.2d 207, 210 (8th Cir. 1987).

[14] *E.g.*, *Kremen v. Cohen*, 325 F.3d 1035, 1041 (9th Cir. 2003) (certifying a question with no district court request); *Torres v. Goodyear Tire & Rubber Co.*, 867 F.2d 1234, 1239 (9th Cir. 1989) (same).

b. Plaintiffs always opposed the district court's misguided decision to resolve Defendants' innovator liability motion in the abstract.

Defendants represent that the Plaintiffs "urg[ed] the district court to decide the state-law issues itself," Brand.Br. at 136, but nothing could be further from the truth. The issue arose for the first time in August 24, 2020, when *Defendants* filed a 15-page motion to dismiss claiming—with essentially no analysis of particular states' laws—that claims under *any count* should be dismissed to the extent it is asserted by a plaintiff who consumed generic ranitidine and then sued a Brand Defendant. *See* MDL.Dkt.1585. They argued for dismissal of "all innovator-liability claims" whether in "individual complaints, the MPIC, or Short Form Complaints." *Id.* at 20. The motion never cited *Erie* or told the district court that it must make an *Erie* guess. Rather, it asserted that if there was not an on-point decision *expanding* liability, the claim must be rejected as "out of step with tort law." *Id.* at 9.

The motion was entirely unclear *which* claims by *which* plaintiffs were even implicated. The motion came just three days after the deadline for plaintiffs with individual pleadings to file short-form complaints. *See* MDL.Dkt.1496 at 4. The statute of limitations for Zantac claims would not run for more than a year, and claims were being filed at an increasing clip. At this point, the parties and the Court did not know which states the Plaintiff population was from (or which district court

they chose as their venue). Worse, the motion argued that the court lacked personal jurisdiction but asked it to exercise jurisdiction by dismissing claims on the merits.

Plaintiffs *always* opposed Defendants' premature, blunderbuss approach. Proper resolution of the motion required plaintiff-specific facts (such as what marketing the plaintiff saw, which drugs they took, which state they live in, and choice of law). Instead, Defendants relied on *Erie* conservatism on the merits, and, for personal jurisdiction, "their unsupported assertion that their 'labeling decisions occurred at their principal places of business,'" when "the MPIC d[id] not support this made up fact." MDL.Dkt.1973 at 27. Objecting to Defendants' unreasonable motion, Plaintiffs asked the court *not* to proceed: "The Court should conduct the analysis with *specific plaintiffs* for *specific cases* armed with full briefing on each state's foreseeability doctrine." MDL.Dkt.1973 at 11 (emphasis added). The response also objected that case-specific analysis of "Defendants' labeling, sales, and advertising practices" were needed, and an opportunity "to disprove their denials of any connection to the forum." *Id.* at 26.

Given the *complete* lack of state-specific briefing, Defendants' challenge to personal jurisdiction, and the objections Plaintiffs had to litigating the issue in general (rather than for specific cases), it would have been absurd to request certification to dozens of state courts. Even though Plaintiffs believed the Court should simply have deferred the issue, they can hardly be blamed for including a

merits argument. And so the response correctly pointed out (as Defendants had failed to point out) that *if* the Court insisted on reaching the question, it could not rely on claims being out-of-step with tort law but needed to "make an *Erie* guess." MDL.Dkt.1973 at 13 (capitalization normalized). Over Plaintiffs' objections, the district court then "*sua sponte*" ordered supplemental briefing of "no more than two (2) double spaced pages" for each state. MDL.Dkt.2228 at 1-2. It then decided the issue, giving Defendants everything they asked for, including nonsensically ruling on the merits *first*, and then personal jurisdiction *second*. MDL.Dkt.2516.

c. Certification is the wisest course.

Defendants question the practicality of certifying questions to various courts, but this case is the most practical and efficient way to resolve this longstanding, confusing area of law. Perhaps it would "take years" for every court to resolve the question, but that is far less time than it would take for the issue to be resolved in dozens of states in the absence of certification. Delay is never good, but it can be more or less costly. Here, there is no appeal bond accruing interest. The attorney teams have a deep bench and are uniquely capable of briefing dozens of appeals. Certification to thirty-two state supreme courts may seem substantial, but it is fairly modest in comparison to the thousands of cancer victims whose recoveries are at issue.

Defendants cite "another MDL that included innovator-liability claims" back in 2012 that declined certification of twenty-two states based on the time it would take, but that well-illustrates the problem. Brand.Br. at 139-40. Twelve years later, there is still precious little state case law. The issue arises in federal court all the time—and especially in multi-district litigation—but rarely in state court. Declining to certify simply means the issue remains uncertain, forever. Worse, with MDL courts (and appeals from MDL courts) resolving the issue, the nuances of state law are lost. It is no coincidence that MDL courts tend to simply default to saying no state would accept liability under *Erie* conservatism—the eyes glaze over by the fifteenth *Erie* guess.

This Court's precedents favor certification. This is an important, unsettled issue of state law that arises frequently, but on which most states have zero case law. Certification is exactly the tool for the job.

C. The District Court's *Erie* Guesses Were Erroneous.

Brand Defendants understandably see no problem with the stark difference between federal predictions about state law and what state supreme courts actually do—that is presumably because it benefits them. But the Supreme Court has recognized that any distinction between federal predictions and state practice countermands the twin goals of *Erie*. The summary-execution-style *Erie* guess that the district court conducted here should be rejected.

Defendants at first claim that the district court did not employ *Erie* conservatism, but ultimately are forced to argue their real position: "Unless and until a state supreme court" expressly recognizes a duty "so that users of generic drugs may sue brand-name manufacturers . . . a federal court must proceed with extreme caution before concluding that innovator-liability claims are cognizable in that jurisdiction." Brand.Br. at 142. And "extreme caution" means simply not to do it. That approach failed to predict California law; it failed to predict Massachusetts law; and it will fail to predict the law of a large number of other states too. The fact is, when state supreme courts have considered this question, they have uniformly treated it as a close question, with a supermajority of justices accepting liability. The extreme skepticism Defendants advocate (and that the district court accepted) is unwarranted.[15]

As for Illinois in particular, Defendants hardly bother engaging with any arguments.[16] They cite *federal* cases but ignores the multiple federal cases that have

[15] Brand Defendants cite a "Scorecard: Innovator Liability" from the Drug and Device Law blog but omit its paeon to *Erie* conservatism. *See* James M. Beck, *Why Erie Is an Inherently Conservative Doctrine*, Drug & Device Law (Nov. 11, 2019), https://www.druganddevicelawblog.com/2019/11/why-erie-is-an-inherently-conservative-doctrine.html.

[16] Defendants cite two trial-court orders, but omit their facts, which explained the ruling. That is why multiple rulings by the same court have *upheld* innovator liability, which has now been accepted in jury instructions in *two* separate Zantac trials. *See* Ex. 8 (denying Defendants' motion as to Count III); Hr'g Tr. Vol. 26 at

predicted Illinois would adopt the theory. The only two Illinois cases address market share liability and a strict product liability case, neither of which have anything to do with negligent misrepresentation (which Illinois has adopted). It does not defend the district court's citation of Stephen Schwartz, who has been a terrible barometer of Illinois law. It does not address Illinois foreseeability law, the opening brief's discussion of Illinois's *eagerness* to innovate in tort law, or the *defense bar's* characterization of Illinois courts as "hellholes" for their liability-expanding penchant.

Rather, Defendants lean *hard* on a federal-court consensus that so-called "innovator liability" is self-evidently absurd. That is *Erie* conservatism in a nutshell, and this Court must reject it.

CONCLUSION

The judgments below should be vacated, with instructions to dismiss for lack of jurisdiction. If the Court upholds jurisdiction, the judgments should be reversed and remanded for trial.

3228:2-3237:9, *Gross v. Boehringer Ingelheim Pharms., Inc.*, No. 2023-L-000469 (Ill. Cir. Ct. Cook Cnty. Aug. 1, 2024) (Exhibit 11); Trial Tr. Vol. 36 at 5021:8–5027:1, *Valadez v. GlaxoSmithKline LLC*, No. 2020-L-0000483 (Ill. Cir. Ct. Cook Cnty. May 21, 2024) (Exhibit 12); Hr'g Tr. at 115:5-13, *Banna v. Walgreen Co.*, No. 2020-L-004916 (Ill. Cir. Ct. Cook Cnty. Aug. 17, 2023) (Exhibit 13).

Dated: November 8, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation allowed by this Court's Order, Dkt.137-1 at 3, because it contains 14,000 words, excluding the parts exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a) because it has been prepared in a proportionately spaced typeface using Microsoft Word Times New Roman 14-point font.

Dated: November 8, 2024

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CERTIFICATE OF SERVICE

On November 8, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. All participants in this case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

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